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| 10/782,459 | 02/19/2004 | Barry J. Maurer | 9022-42 | 4853 |

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| EXAMINER | |
|---|---|
| HENLEY III, RAYMOND J | |
| **ART UNIT** | **PAPER NUMBER** |
| 1614 | |

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**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 10/782,459 | MAURER ET AL. | |
| | Examiner | Art Unit | |
| | Raymond J. Henley III | 1614 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) *1-37* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☒ Claim(s) *20-29,31 and 32* is/are allowed.

6)☒ Claim(s) *1-7, 10, 12-14,16-19 and 30* is/are rejected.

7)☒ Claim(s) *8,9,11,12,15 and 33-37* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

**Application Papers**

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☒ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *2/2/2005*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

**CLAIMS 1-37 ARE PRESENTED FOR EXAMINATION**

Applicants' Information Disclosure Statement filed February 2, 2004 has been received and entered into the application. As reflected by the attached, completed copy of form PTO-1449, (1 sheet, "substitute form"), the cited references have been considered.

***Oath/Declaration***

The oath or declaration is defective. A new oath or declaration in compliance with 37 CFR 1.67(a) identifying this application by application number and filing date is required. See MPEP §§ 602.01 and 602.02.

The oath or declaration is defective because at page 1, the benefit of Provisional Application No. 60/444,536, filed February 21, 2003 is indicated. This serial number is incorrect and Office records indicate that the serial number should be "60/449,536".

Appropriate correction is required.

***Specification***

The disclosure is objected to because page 1 does not contain a statement that a claim for benefit is made based on Provisional Application Serial No. 60/449,536, filed February 21, 2003, (according to Office records).

Appropriate correction is required.

***Claim Objection***

Claim 12 is objected to because at step "(c)", reference is incorrectly made to step "(c)" instead of a product produced by a previous step.

Appropriate correction is required.

Claims 8, 9, 11, 15 and 33-37 are objected to as depending from a rejected base claim, but are otherwise in condition for allowance.

***Allowable Subject Matter***

Claims 20-29, 31 and 32 are deemed in condition for allowance for the reasons explained below.

***Claim Rejection - 35 USC § 112, First Paragraph***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 13, 14 and 16-19 and 30 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the treatment of the cancers disclosed in, for example, claim 15, does not reasonably provide enablement for the treatment of "cancer" in general. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

The present specification is evaluated by the Examiner as directed by the Court in *In re Marzocchi et al.* , 169 USPQ 367 (CCPA 1971):

"Specification disclosure which contains teaching of manner and process of making and using the invention in terms corresponding to the scope to those used in describing and defining subject matter sought to be patented must be taken as in compliance with enabling requirement of first paragraph of 35 U.S.C. 112 *unless there is reason to doubt the objective truth of statements contain therein which must be relied on for enabling support*; assuming that sufficient reason for such doubt exists, a rejection for failure to teach how to make and/or use will be proper on that basis, such a rejection can be overcome by suitable proofs indicating that teaching contained in specification is truly enabling." (emphasis added).

Here, the objective truth of the statement that "cancer" in general may be treated is

doubted because, while the state of the art of cancer treatment is well developed with regard to the treatment of specific cancer types (see the Cecil reference newly cited by the Examiner at pages 1060-74), the state of the art with regard to treating cancer broadly is underdeveloped. In particular, there is no known anticancer agent or combination of anticancer agents that is effective against all cancer types. The Cecil reference clearly shows that for the various known cancer types, there is not one specific chemotherapeutic agent or combination thereof that is effective for each and every type of cancer (see page Table 198-5 at page 1065; Tables 198-6 and 198-7 at page 1066; Table 198-8 at page 1068; and Table 198-9 at page 1071).

In light of the fact that there is no one particular agents or combination of agents known to be effective for the treatment of all cancer types which constitute the term "cancer", the claimed recitation of "cancer" is insufficient to enable one of ordinary skill in the art to practice the instant invention with a reasonable expectation of success. In order for the skilled artisan to practice the treatment of "cancer" in general, there would be placed on said artisan an undue burden of determining which types of cancer from those known would be amenable to treatment with the presently disclosed compositions.

***Suggestion for Overcoming this Rejection***

Claims 13 and 30 should be amended to include a Markush grouping of the cancers as in present claim 15 in order to overcome this rejection.

***Claim Rejection - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person

having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-7, 10 and 12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ferrandis et al., (U.S. Patent Application No. 2005/0181999, cited by the Examiner).

Ferrandis et al. teach topical dermatological compositions comprising a sphingolipid, lactic acid and a solvent which may be an alcohol such as ethanol, (see the abstract; paragraph [0033], and at page 6, claims 1, 4, 7 and 8). Also, it is disclosed that the compositions are stable over time, (paragraph [0083]).

The differences between the above and the claimed subject matter lies in that the reference fail to highlight each of the presently claimed sphingolipid compounds, the present method of making the composition and the particular amounts/proportions of ingredients.

However, the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains because the reference teaches "spingolipids" in a non-limiting manner thus indicating that in order to practice the invention of the reference, one may select from the known sphingolipids and

employ these compounds in the manner taught for "spingolipids".

Also, the skilled artisan would have found it obvious to follow various procedure to mix the intended ingredients together in order to produce a final product, i.e., solution. The determination of any particular mixing sequence would have been within the purview of the artisan and the artisan would have been motivated to do so in order to produce a final product that is effective for the purposes intended.

Also, it is well recognized that "Generally, differences in concentration or temperature will not support the patentability of subject matter encompassed by the prior art unless there is evidence indicating such concentration or temperature is critical. "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." *In re Aller*, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955)" (see MPEP 2144.05(II)).

The determination of the optimum dosage regimen to employ with the presently claimed active agents would have been a matter well within the purview of one of ordinary skill in the art and such determination would have been made in accordance with a variety of factors. These would have included factors such as the medical condition being treated, (e.g., see paragraph [0057], and the severity of the condition.

Here, it is not seen that Applicants' have indicated the proportioning of ingredients to be critical, thus the claims are deemed properly rejected.

***Claims 20-37 Appear Allowable***

Claims 20-37 are directed to an emulsion compositions comprising lactic acid, a sphingolipid, optionally an isotonic agent and a phospholipid, (interpreted by the Examiner as

not being apart of the "optionally" indication. Also claimed is a method of making the compositions and a method of treating cancers by administering the composition to a subject in need thereof.

The closest art discovered by the Examiner is Herstein, (U.S. Patent No. 5,616,332, cited by the Examiner). Herstein teaches a cosmetic/pharmaceutical composition comprising a sphingosine "material", (col. 2, lines 14-15), which may be a D(+)-erythro enantiomer of such material and also may include analogs, homologs, enantiomers and derivatives of sphingosine, (col. 5, lines 7-22). Also included in the composition is lactic acid, (col. 5, line 60) and ethanol, (col. 8, lines 43). That the compositions are stable, the patentees teach the inclusion of a stabilizer, (col. 8, line 60). While an "emulsion" is not highlighted, it is believed that such would have at least been suggested by the other variety of aqueous/lipid or hydrophilic/hydrophobic types of compositions, namely creams, lotions, tonics "and the like", (col. 8, lines 42-43).

The present claims require the presence of a phospholipid compound. Herstein, however, teaches away from including a phospholipid because the patentees observed that phospholipids did not possess an ability to increase cell renewal and thus was no of significant commercial interest, (see col. 12, Table 1 and the discussion thereafter at lines 16-27).

Accordingly, subject matter defined in present claims 20-37 are deemed free of art.

The references cited on the attached form PTO-892 and not relied on are cited to show the general state of the art.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Raymond J. Henley III whose telephone number is 571-272-0575. The examiner can normally be reached on M-F, 8:30 am to 4:00 pm Eastern Time.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin H. Marschel can be reached on 571-272-0718. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Raymond J Henley III
Primary Examiner
Art Unit 1614

June 18, 2007